

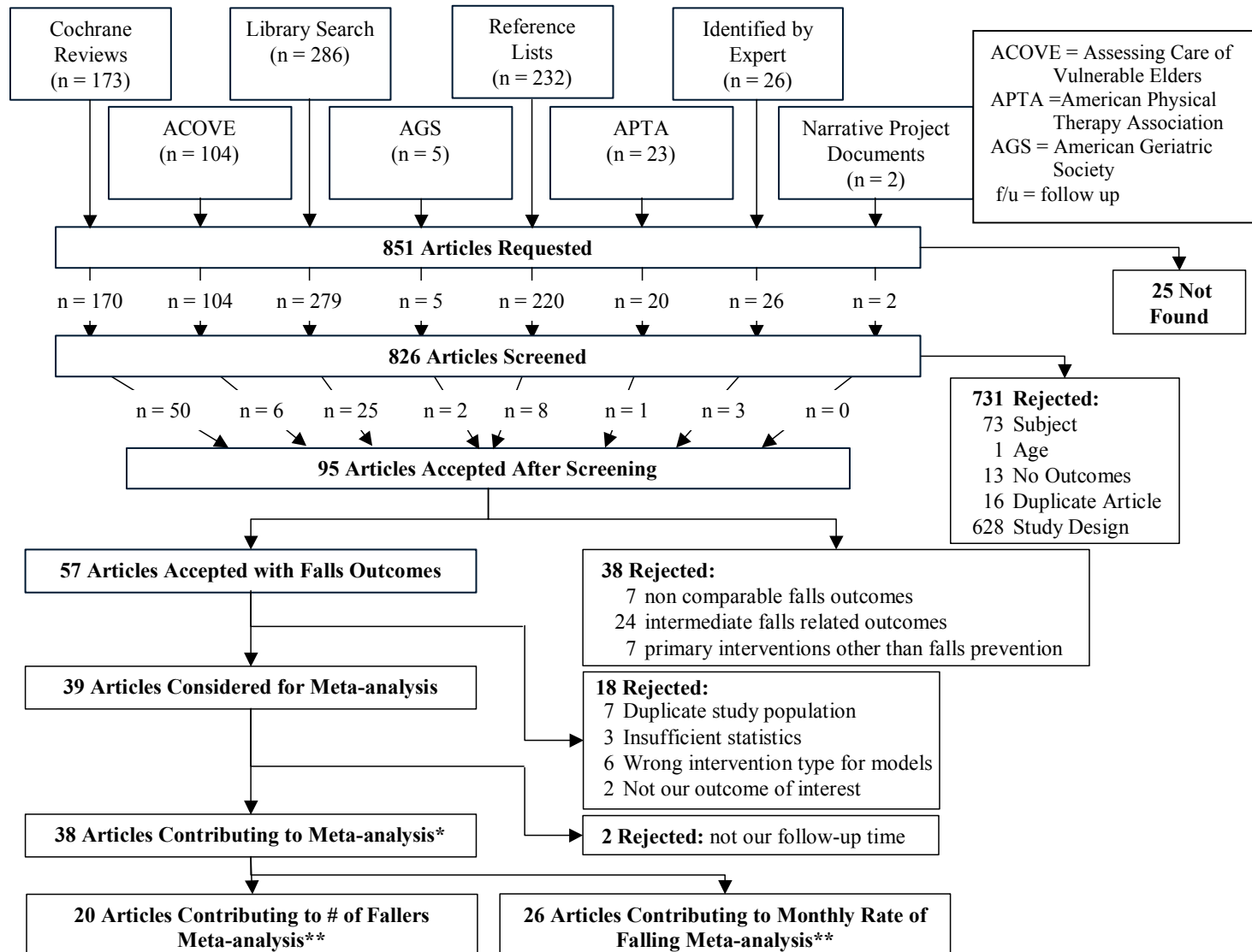
RESULTS

Identification of Evidence

Figure 4 describes the flow of evidence from the original sources to final acceptance for our review. The Cochrane Collaboration provided 173 relevant citations, while the Assessing Care of the Vulnerable Elderly (ACOVE) Project files contained 104 possibly relevant additional articles. Another five articles were sent to us by the American Geriatric Society (AGS), and the American Physical Therapy Association (APTA) sent us 23 article abstracts. We found two CMS Narrative Project Documents regarding falls prevention. A library search yielded 286 articles not previously noted; 232 additional articles were found by examining the reference lists of all articles we obtained. Twenty-six additional articles were obtained from experts. In total, the above sources yielded 851 articles, but we were unable to obtain 25 of these. This left 826 articles for the screening process.

Of the 826 articles screened, 73 did not discuss falls prevention. Six hundred twenty-eight were rejected because they were not randomized controlled trials (RCTs) or controlled clinical trials (CCTs). Another 16 articles were duplicates of articles already on file. Thirteen others did not include outcomes; i.e. they were simply descriptions of a falls prevention study in progress. One article did not study the age of interest. This left 95 articles for quality review.

Figure 4. Article Flow



* These 38 articles include one study originally rejected as Review (see text for complete description).

** These numbers are not mutually exclusive as some articles contributed to more than one analysis.

Selection of Studies for the Meta-Regression Analyses

Following the initial screening, we reviewed the articles retrieved from the literature sources to determine whether to include them in the evidence synthesis. We created a one-page screening review form to record the subject, study design, age of the study participants, and type of outcomes from each article.

Studies were included for further review after meeting three major inclusion criteria. First, a study had to have falls prevention as a principal objective. Second, while we were searching primarily for data relevant to the Medicare population, we also included studies containing data on participants age 60 and older to avoid losing potentially useful articles. Third, a study had to be either a randomized controlled trial (RCT) or controlled clinical trial (CCT). We employed this restriction on study design in order to maximize our ability to evaluate whether differences in outcomes could be attributed to the interventions being studied. We created an eight-page quality review and abstraction form to collect detailed information about the interventions and outcomes used in each study (Figure 3).

Of the 95 controlled trials that underwent quality review, 38 provided only outcomes other than falls or falls reduction was not the principal aim of the study (such as studies of hormone replacement therapy whose primary outcome was bone density assessments but may have also report falls). Since the focus of this project was the systematic review of interventions for the prevention of falls, only the 57 studies that provided falls outcomes were reviewed for potential inclusion in the meta-regression. We abstracted data on how falls were reported in the studies, the follow-up times, and the study populations.

In order to maximize the inclusion of studies with common outcomes in the meta-regression, we examined how falls outcomes were reported. We discovered that the most widely reported falls outcome among the accepted studies was “subjects who fell at least once during the study period.” The second most commonly reported outcome was a measure of falls rate, such as the monthly rate of falling per person. Three of the 61 studies were excluded because they did not provide data on outcomes by intervention and control group. Additionally, seven of the 61 studies were rejected when the study populations were determined to be already in the analysis through another publication (only one article from the same study population could be included in the meta-analysis). Six studies were excluded as the intervention type was not represented in our conceptual model. Two studies were excluded because they did not report either of our outcomes of interest. This left 39 studies which were considered for meta-analysis. Table 3 reports the follow-up time points that were measured in the remaining studies.

Table 3. Follow-up Periods for Articles with Falls Outcomes

| Study | 3 Months | 12 Months (6-18 months) | 24 Months | Greater than 24 Months |
|--------------------------------|----------|----------------------------|-----------|---------------------------|
| Buchner DM, 1997 ID #617 | | X (7-18) | | |
| Campbell AJ, 1997 ID #483 | | X | | |
| Campbell AJ, 1999a ID #1504 | | X | X | |
| Campbell AJ, 1999b ID #1593 | | X (11) | | |
| Carpenter GI, 1990 ID #443 | | | | X |
| Cerny K, 1998 ID #717 | | X (6) | | |
| Close J, 1999 ID #1524 | | X | | |
| Coleman EA, 1999 ID #1510 | | X | X | |
| Crome P, 2000 ID #3633 | | X (6) | | |
| Cumming RG, 1999 ID #1699 | | X | | |
| Ebrahim S, 1997 ID #1204 | | X | X | |
| El Faizy, 1994 ID #583 | | X (9) | | |
| Fabacher D, 1994 ID #444 | | X | | |
| Fiatarone, 1993 ID # 528 | | X (18) | | |
| Gallagher EM, 1996 ID #578 | | X (6) | | |
| Hornbrook MC, 1994 ID #445 | | | X (23) | |
| Jensen J, 2002 ID #3654 | | X (8.5) | | |
| Jitapunkul S, 1998 ID#3604 | | | | X |
| Lord SR, 1995 ID #446 | | X | | |
| Mayo NE, 1994 ID #448 | | X | | |
| McMurdo ME, 1997 ID #449 | | | X | |
| McMurdo ME, 2000 ID #1984 | | X (7-12) | | |
| McRae PG, 1994 ID #2027 | | X | | |
| Means KM, 1996 ID #450 | | X (6) | | |

Table 3. Follow-up Periods for Articles with Falls Outcomes

| Study | 3 Months | 12 Months (6-18 months) | 24 Months | Greater than 24 Months |
|-----------------------------------|-----------------|------------------------------------|------------------|-----------------------------------|
| Millar AM, 1999 ID #3617 | X (4) | X (6) | X | |
| Mulrow CD, 1994 ID #451 | | | | |
| Pereira MA, 1998 ID #1533 | | X | | |
| Reinsch S, 1992 ID #491 | | X | | |
| Robertson MC, 2001 ID #3260 | X | X | | |
| Rubenstein LZ, 1990 ID #492 | | X | | |
| Rubenstein LZ, 2000 ID #1988 | | | | |
| Ryan JW, 1996 ID #681 | | | | |
| Salkeld, 2000 ID #3094 | X | X | | |
| Schoenfelder DP, 2000 ID #3624 | | X (6) | | |
| Steinberg M, 2000 ID #2523 | | X | | |
| Tinetti ME, 1994 ID #494 | | X | | |
| Van Haastregt J, 2000 ID #3091 | | X X (18) | | X |
| Vetter NJ, 1992 ID #501 | | | | |
| Wagner EH, 1994 ID #502 | | X | | |
| Wolf SL, 1996 ID #503 | | X (8) | | |
| | 3 | 32 | 7 | 3 |

Our first analysis included all studies that reported sufficient data on the number of people who fell at least once. We found 22 studies that reported this with follow-up times ranging from 3 to 24 months. As the effectiveness of the intervention may not be stable over time, we examined the relative effectiveness of falls prevention interventions in those studies that reported multiple time points. Table 4 shows those studies that presented data at multiple time points. Again, this table is restricted to those studies that reported the number or percent of patients who fell at least once. Both the time point at which the data are collected (column labeled “Data collection point”) and the period over which the data are collected (column labeled “Accumulation time period”) are displayed. We note that these two times may be different. For example, at six months after the study began, a study might report data for the number of patients who fell at least once during the previous three months, i.e., between three and six months.

Table 4 shows the risk ratio and associated 95% confidence interval for each study with multiple time points. This risk ratio represents the risk of a person falling at least once as compared to the risk for a person in the control or usual care group. The key message from the table is that within and across studies, the risk ratios do not stay constant, nor do they increase or decrease consistently over time.

Table 4. Studies with Multiple Time Point Measures

* Note: Total reported is sum of respondents in each accident group

| Author | Group | N | Data Collection Point | Accumulation Time Period | # People who had at Least One Fall | Risk Ratio (95% C.I.) |
|--------------------------|--------------|-----|-----------------------|--------------------------|------------------------------------|-----------------------|
| Bowling, 1992 ID#513 | Hosp. Ward | 48 | 3 months | 3 months | 11 | 0.76 (0.39, 1.49) |
| | Nursing Home | 50 | 3 months | 3 months | 15 | |
| | Hosp. Ward | 38 | 6 months | 3 months | 6 | 0.29 (0.13, 0.64) |
| | Nursing Home | 38 | 6 months | 3 months | 21 | |
| | Hosp. Ward | 29 | 9 months | 3 months | 4 | 0.31 (0.11, 0.82) |
| | Nursing Home | 31 | 9 months | 3 months | 14 | |
| | Hosp. Ward | 49* | 12 months | 3 months | 18 | 0.53 (0.35, 0.80) |
| | Nursing Home | 52* | 12 months | 3 months | 36 | |
| Coleman, 1999 ID#1510 | Intervention | 79 | 12 months | 12 months | 34 | 1.13 (0.75, 1.69) |
| | Control | 63 | 12 months | 12 months | 24 | |
| | Intervention | 78 | 24 months | 12 months | 34 | 1.26 (0.79, 1.99) |
| | Control | 49 | 24 months | 12 months | 17 | |
| Ebrahim, 1997 ID#1204 | Intervention | 52 | 12 months | 12 months | 22 | 1.18 (0.72, 1.91) |
| | Control | 50 | 12 months | 12 months | 18 | |
| | Intervention | 49 | 24 months | 12 months | 17 | 0.93 (0.54, 1.57) |
| | Control | 48 | 24 months | 12 months | 18 | |

Table 4. Studies with Multiple Time Point Measures

* Note: Total reported is sum of respondents in each accident group

| Author | Group | N | Data Collection Point | Accumulation Time Period | # People who had at Least One Fall | Risk Ratio (95% C.I.) |
|--------------------------------|--------------|-----|-----------------------|--------------------------|------------------------------------|-----------------------|
| Rubenstein, 1990 ID#492 | Intervention | 79 | 12 months | 12 months | 56 | 0.94 (0.78, 1.14) |
| | Control | 81 | 12 months | 12 months | 61 | |
| | Intervention | 79 | 24 months | 12 months | 64 | 0.97 (0.84, 1.11) |
| | Control | 81 | 24 months | 12 months | 68 | |
| Van Haastregt, 2000 ID#3091 | Intervention | 129 | 12 months | 12 months | 63 | 1.13 (0.87, 1.48) |
| | Control | 123 | 12 months | 12 months | 53 | |
| | Intervention | 120 | 12 months | 12 months | 68 | 1.12 (0.88, 1.43) |
| | Control | 115 | 12 months | 12 months | 58 | |
| Wagner, 1994 ID#502 | Intervention | 635 | 12 months | 12 months | 175 | 0.75 (0.64, 0.88) |
| | Usual Care | 607 | 12 months | 12 months | 223 | |
| | Intervention | 635 | 24 months | 12 months | 199 | 1.07 (0.91, 1.27) |
| | Usual Care | 607 | 24 months | 12 months | 177 | |

Given this lack of empirical information on the stability of intervention effectiveness over time, we used expert judgment to determine that falls occurring between six and 18 months post-intervention were sufficiently clinically similar to support statistical pooling. Therefore, studies were included in the meta-analysis if the study reported data on “subjects who fell at least once during the study period,” and the study included follow-up data at a time point between six and 18 months. Two studies without data during this time period were excluded; therefore, 20 studies were included in this analysis.

MONTHLY RATE OF FALLING

In this second analysis, we restricted attention to those studies that provided the total number of falls and the average follow-up period in each arm (treatment and control or usual care), which would allow calculation of monthly falls rates per subject. The follow-up times varied greatly across studies, from as little as one month on average of follow-up to as much as 38 months. We included all studies that provided sufficient statistics for analysis regardless of follow-up period. Twenty-five studies provided sufficient

statistics. We compared our pool of studies with those used in the FICSIT trial. Five of the 7 FICSIT sites were included in our pool of studies. Two had been excluded at the screener stage because they were descriptive papers. We decided to use the data reported in the FICSIT paper for one of the studies.³⁸ We decided to exclude the results from the other FICSIT article³⁹ as it truncated the number of falls. Therefore, 26 studies contributed to the analysis of falls rate.

Controlled Trials Excluded from the Meta-Regression Analyses

Excluded studies fall into eight major categories:

1. RCTs with non-comparable falls outcomes
2. RCTs with intermediate “falls-related” outcomes
3. RCTs with primary interventions other than falls prevention
4. Multiple published reports on the same study
5. RCTs with insufficient statistics
6. RCTs evaluating interventions outside of our conceptual model
7. RCTs reporting an outcome not of interest in this analysis
8. RCTs outside our range of follow-up times

We present a qualitative summary of these studies below.

RCTs WITH NON-COMPARABLE FALLS OUTCOMES

We identified seven studies⁴⁰⁻⁴⁶ that reported at least one falls outcome, but either the type of outcome measured or how the outcome was reported was not comparable to nor poolable with our outcomes of interest. Therefore, these studies were not included in the meta-analysis. One⁴¹ study reported the number of “accidents” which included falls, but also included other causal factors. Another study⁴² measured falls only as an outcome as part of a platform sensory test; not falls outside of the balance testing environment. Most of the other studies either did not provide adequate information about the number of unique persons falling in each group or the numbers provided were not poolable with our outcomes of interest. The types of interventions among these studies varied and included balance and strength training, hormone replacement therapy, nutritional supplementation, and selecting a specific location for care.

RCTs WITH INTERMEDIATE FALLS RELATED OUTCOMES

We identified twenty-four studies⁴⁷⁻⁷⁰ that did not report falls but reported falls-related outcomes. Most of these studies included exercise interventions and primarily measured exercise performance measures, such as performance time, balance, strength, and

flexibility; and functional measures, such as fear of falling and self-rated falls risk. One study⁷⁰ focused on the use of hip protectors to improve falls self-efficacy.

RCTs WITH PRIMARY INTERVENTIONS OTHER THAN FALLS PREVENTION

We identified seven studies⁷¹⁻⁷⁷ that have implications for falls prevention, but contained primary interventions other than falls prevention. Three studies^{74, 75, 77} studied calcium and vitamin D on the outcomes of hip fractures, other fractures, and bone mineral density. One study⁷¹ studied the effect of hormone replacement therapy on functional balance. One study⁷² studied the effect of diazepam on balance and neurocognitive tests. One study⁷³ studied the effect of physical therapy on mobility in patients with dementia.

MULTIPLE PUBLISHED REPORTS ON THE SAME STUDY

We identified seven publications that reported results of study populations already included in the meta-analysis⁷⁸⁻⁸⁴ via another publication^{16, 37, 85-88}.

RCTs WITH INSUFFICIENT STATISTICS

Three studies were excluded from the meta-analyses because they did not report the necessary statistics. Two studies^{89, 90} reported falls for the entire study population, but not by intervention group. A third study only reported falls for the treatment group. None were reported for the control group.⁹¹

RCTs EVALUATING INTERVENTIONS OUTSIDE OUR CONCEPTUAL MODEL

Six studies reported on interventions that were not included in our conceptual model. The interventions were bed alarm systems,⁹² physical restraints,⁸⁵ “hospital-in-the-home,”⁴⁴ home rehabilitation,⁹³ use of a medication (Raubasine-Dihydroergocristine),⁹⁴ and cardiac pacing for carotid sinus syndrome.⁹⁵

RCTs REPORTING AN OUTCOME NOT OF INTEREST IN THIS ANALYSIS

Two studies reported a falls outcome other than monthly falls rate or number of people who fell at least once. These studies only reported on the number of recurrent fallers.^{96, 97}

RCTs OUTSIDE OUR RANGE OF FOLLOW-UP TIMES

Seven studies were rejected from the percent of fallers analysis because the follow-up times reported were outside of six to eighteen months (the time conceptualized by our study to be comparable). Five studies^{35, 98-101} reported both number of subjects with at least one fall and percent of fallers. These five studies contributed to the number of subjects with at least one fall analysis but not to the percent of fallers analysis. Two studies^{102, 103} reported only percent of fallers with a followup time greater than 24 months and therefore were excluded from the analysis. The types of interventions among these studies were exercise programs, education, and home visits.

The majority of exclusions from the meta-analyses were due to the use of falls outcomes that we judged clinically too heterogeneous to support pooling. This finding suggests that future research would benefit from the development of a consensus outcome measure for falls (e.g. percentage of subjects falling during follow-up period or monthly rate of falling). While future research in falls prevention and exercise may include a number of outcomes, ensuring the inclusion of at least one consensus measurement for falls would allow for easier comparisons and enhanced information, by ensuring inclusion of all future trials into pooled analyses.

Table 5 displays randomized falls prevention trials excluded at the final decision point. Thus 38 studies remained for inclusion in the meta-analysis, 20 contributing to the “subjects who fall at least once” analysis and 26 contributing to the monthly rate of falling per person analysis. Some studies contributed data to both analyses. These studies are listed in Table 6.

Table 5. Studies Excluded from Meta-Regression Analyses

| Author, Year | Reason for Exclusion |
|-------------------------------------|--|
| Armstrong AL, 1996 ID#576 | Doesn't report people w/ at least one fall or falls rate |
| Capezuti EA, 1995 ID#1316 | Intervention type not in conceptual model – restraints |
| Capezuti, 1998 ID#621 | Duplicate data of study Capezuti, 1995 ID#1316 |
| Gardner, 1998 ID#1297 | Duplicate data of study Campbell, 1999a ID#1504 |
| Jitapunkul S, 1998 ID#3604 | Wrong follow-up time (3 months) |
| Kannus P et al., 2000 ID#3089 | Insufficient statistics - control outcomes not reported |
| Kenny RA, 2001 ID#3622 | Intervention type not in conceptual model |
| Peel N et al., 1998 ID#3259 | Insufficient statistics - doesn't report outcomes by group |
| Peel N, 2000 ID#3607 | Duplicate data of study Steinberg, 2000 ID#2523 |
| Pereira MA, 1996 ID#3618 | Duplicate data of study Pereira, 1998 ID#1533 |
| Pfeifer M, 2000 ID#3605 | Intervention type not in conceptual model |
| Ray WA et al., 1997 ID#1198 | Doesn't report people w/ at least one fall or falls rate |
| Rizzo, 1996 ID#418 | Duplicate data of study Tinetti, 1994 ID#494 |
| Robertson MC, 2001b ID#3601 | Duplicate data of study Campbell, 1997 ID#483 |
| Tennstedt S et al., 1998 ID#1195 | Insufficient statistics - no valid outcomes, reported mean change scores |
| Tideiksaar R et al., 1993 ID#493 | Intervention type not in conceptual model – bed alarm |
| Tinetti, 1996 ID#497 | Duplicate data of study Tinetti, 1994 ID#494 |
| Vellas B, 1991 ID#3619 | Intervention type not in conceptual model |
| Vetter NJ et al., 1992 ID#501 | Wrong follow-up time |
| Widen Holmqvist L, 1998 ID#3610 | Intervention type not in conceptual model |

Table 6. RCT Studies Included in Meta-Regression Analyses

| | Number or falls rate | % with at least one fall |
|--|-------------------------|-----------------------------|
| Buchner DM, Cress ME, de Lateur BJ, Esselman PC, Margherita AJ, Price R, et al. The effect of strength and endurance training on gait, balance, fall risk, and health services use in community-living older adults. <i>J Gerontol A Biol Sci Med Sci</i> . 1997;52(4):M218-24. ID#617 | X | X |
| Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. <i>BMJ</i> . 1997;315(7115):1065-9. Rec #: 483 | X | X |
| Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM. Falls prevention over 2 years: a randomized controlled trial in women 80 years and older. <i>Age Ageing</i> . 1999a;28(6):513-518. Rec #: 1504 | X | |
| Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM . Psychotropic medication withdrawal and a home-based exercise program to prevent falls: a randomized, controlled trial. <i>J Am Geriatr Soc</i> . 1999b;47(7):850-3. Rec #: 1593 | X | |
| Carpenter GI, Demopoulos GR. Screening the elderly in the community: Controlled trial of dependency surveillance using a questionnaire administered by volunteers. <i>BMJ</i> . 1990;300(6734):1253-6. Rec #: 443 | X | |
| Cerny K, Blanks R, Mohamed O, Schwab D, Robinson B, Russo A, et al. The effect of a multidimensional exercise program on strength, range of motion, balance, and gait in the well elderly. <i>Gait & Posture</i> . 1998;7:185-186. ID#717 | | X |
| Close J, Ellis M, Hooper R, Glucksman E, Jackson S, Swift C, et al. Prevention of falls in the elderly trial (PROFET): a randomised controlled trial. <i>Lancet</i> . 1999;353(9147):93-97. ID#1524 | X | X |
| Coleman EA, Grothaus LC, Sandhu N, Wagner EH . Chronic care clinics: a randomized controlled trial of a new model of primary care for frail older adults. <i>J Am Geriatr Soc</i> . 1999;47(7):775-783. ID#1510 | | X |
| Crome P, Hill S, Mossman J, Stockdale P. A randomised controlled trial of a nurse led falls prevention clinic [abstract]. <i>Journal of the American Geriatrics Society</i> . 2000;48:S78 Rec#: 3633 | X | |
| Cumming RG, Thomas M, Szonyi G, Salkeld G, O'Neill E, Westbury C, et al. Home visits by an occupational therapist for assessment and modification of environmental hazards: a randomized trial of falls prevention . <i>J Am Geriatr Soc</i> . 1999;47(12):1397-402. ID#1699 | | X |

Table 6. RCT Studies Included in Meta-Regression Analyses

| | Number or falls rate | % with at least one fall |
|--|-------------------------|-----------------------------|
| Ebrahim S, Thompson PW, Baskaran V, Evans K. Randomized placebo-controlled trial of brisk walking in the prevention of postmenopausal osteoporosis. <i>Age Ageing</i> . 1997;26(4):253-60. ID#1204 | X | X |
| El Faizy M, Reinsch S. Home safety intervention for the prevention of falls. <i>Phys Occup Ther Geriatr</i> . 1994;12(3):33-49. Rec #: 583 | X | |
| Fabacher D, Josephson K, Pietruszka F, Linderborn K, Morley JE, Rubenstein LZ. An in-home preventive assessment program for independent older adults: A randomized controlled trial. <i>J Am Geriatr Soc</i> . 1994;42(6):630-8. ID#444 | | X |
| Fiatarone MA, O'Neill EF, Doyle N, Clements KM, Roberts SB, Kehayias JJ, et al. The Boston FICSIT study: the effects of resistance training and nutritional supplementation on physical frailty in the oldest old. <i>J Am Geriatr Soc</i> . 1993;41(3):333-7. Rec #: 528 | X | |
| Gallagher EM, Brunt H. Head over heels: Impact of a health promotion program to reduce falls in the elderly. <i>Can J Aging</i> . 1996;15:84-96. Rec #: 578 | X | |
| Hornbrook MC, Stevens VJ, Wingfield DJ, Hollis JF, Greenlick MR, Ory MG. Preventing falls among community-dwelling older persons: Results from a randomized trial. <i>Gerontologist</i> . 1994;34(1):16-23. Rec #: 445 | X | |
| Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and Injury Prevention in older people living in residential care facilities. <i>Ann Intern Med</i> . 2002;136:733-41. Rec#: 3654 | X | X |
| Lord SR, Ward JA, Williams P, Strudwick M. The effect of a 12-month exercise trial on balance, strength, and falls in older women: a randomized controlled trial. <i>J Am Geriatr Soc</i> . 1995;43(11):1198-206. ID#446 | X | X |
| Mayo NE, Gloutney L, Levy AR. A randomized trial of identification bracelets to prevent falls among patients in a rehabilitation hospital. <i>Arch Phys Med Rehabil</i> . 1994;75(12):1302-8. ID#448 | | X |
| McMurdo ME, Mole PA, Paterson CR. Controlled trial of weight bearing exercise in older women in relation to bone density and falls. <i>BMJ</i> . 1997;314(7080):569. Rec #: 449 | X | |
| McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. <i>Gerontology</i> . 2000;46(2):83-87. ID#1984 | X | X |
| McRae PG, Feltner ME, Reinsch SA. A one-year exercise program for older women: Effects on falls, injuries, and physical performance. <i>J Aging Phys Activitiy</i> . 1994;2:127-142. ID#2027 | | X |

Table 6. RCT Studies Included in Meta-Regression Analyses

| | Number or falls rate | % with at least one fall |
|--|-------------------------|-----------------------------|
| Means KM, Rodell DE, O'Sullivan PS, Cranford LA. Rehabilitation of elderly fallers: Pilot study of a low to moderate intensity exercise program. <i>Arch Phys Med Rehabil.</i> 1996;77(10):1030-6. Rec #: 450 | X | |
| Millar AM. A trial of falls prevention. <i>Age and Ageing.</i> 1999;28:15 Rec#: 3617 | | X |
| Mulrow CD, Gerety MB, Kanten D, Cornell JE, DeNino LA, Chiodo L, et al. A randomized trial of physical rehabilitation for very frail nursing home residents. <i>JAMA.</i> 1994;271(7):519-24. Rec #: 451 | X | |
| Pereira MA, Kriska AM, Day RD, Cauley JA, Laporte RE, Kuller LH. A randomized walking trial in postmenopausal women: effects of physical activity and health 10 years later. <i>Arch Intern Med.</i> 1998;158(15):1695-1701. ID#1533 | | X |
| Reinsch S, MacRae P, Lachenbruch PA, Tobis JS . Attempts to prevent falls and injury: A prospective community study. <i>Gerontologist.</i> 1992;32(4):450-6. ID#491 | | X |
| Robertson MC, Devlin N, Gardner MM, et al. Effectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 1: Randomized controlled trial. <i>BMJ.</i> 2001a;322:697-701. Rec #: 3260 | X | |
| Rubenstein LZ, Robbins AS, Josephson KR, Schulman BL, Osterweil D. The value of assessing falls in an elderly population. A randomized clinical trial. <i>Ann Intern Med.</i> 1990;113(4):308-16. ID#492 | | X |
| Rubenstein LZ, Josephson KR, Trueblood PR, Loy S, Harker JO, Pietruszka FM, et al. Effects of group exercise program on strength, mobility and falls among fall-prone elderly men. <i>J Gerontol .</i> 2000;6:M1-M5. Rec #: 1988 | X | |
| Ryan JW, Spellbring AM. Implementing strategies to decrease risk of falls in older women. <i>J Gerontol Nurs.</i> 1996;22(12):25-31. Rec #: 681 | X | |
| Salkeld G, Cumming RG, O'Neill E, Thomas M, Szonyi G, Westbury C. The cost effectiveness of a home hazard reduction program to reduce falls among older persons. <i>Aust NZ J Public Health.</i> 2000;24(3):265-71. Rec #: 3094 | X | |
| Schoenfelder DP. A fall prevention program for elderly individuals. Exercise in long- term care settings. <i>J Gerontol Nurs.</i> 2000;26:43-51. Rec#: 3624 | X | |
| Steinberg M, Cartwright C, Peel N, Williams G. A sustainable programme to prevent falls and near falls in community dwelling older people: results of a randomised trial. <i>J Epidemiol Community Health.</i> 2000;54(3):227-32. Rec #: 2523 | X | |
| Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. <i>N Engl J Med.</i> 1994;331(13):821-7. ID#494 | X | X |

Table 6. RCT Studies Included in Meta-Regression Analyses

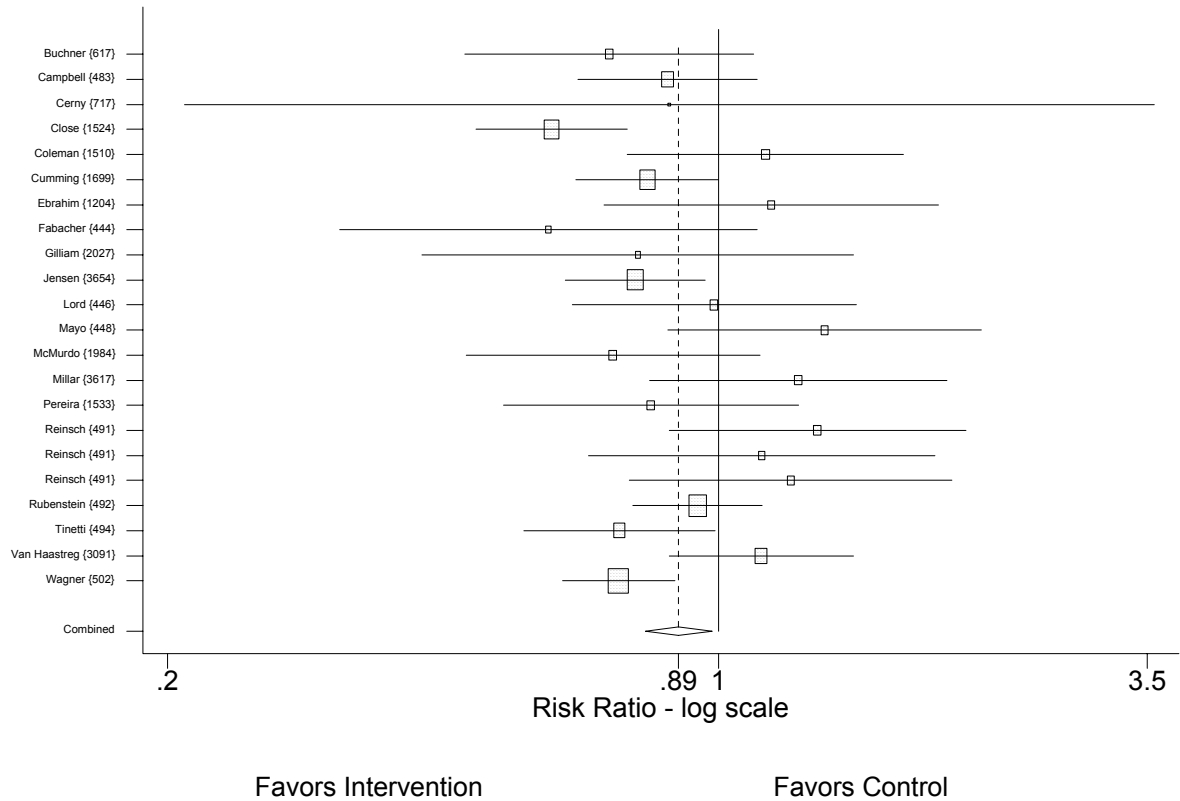
| | Number or falls rate | % with at least one fall |
|---|---------------------------------|-------------------------------------|
| van Haastregt J, Diederiks J, Crebolder H. Effects of a programme of multifactorial home visits on falls and mobility impairments in elderly people at risk: randomised controlled trial. <i>BMJ</i> . 2000;321(7267):994. ID#3091 | | X |
| Wagner EH, LaCroix AZ, Grothaus L, Leveille SG, Hecht JA, Artz K, et al. Preventing disability and falls in older adults: A population-based randomized trial. <i>Am J Public Health</i> . 1994;84(11):1800-6. ID#502 | | X |
| Wolf SL, Barnhart HX, Kutner NG, McNeely E, Coogler C, Xu T. Reducing frailty and falls in older persons: an investigation of Tai Chi and computerized balance training. Atlanta FICSIT Group. Frailty and Injuries: Cooperative Studies of Intervention Techniques. <i>J Am Geriatr Soc</i> . 1996;44(5):489-97. Rec #: 503 | X | |

Responses to Questions Specified by CMS

QUESTION 1. ARE FALLS PREVENTION PROGRAMS EFFECTIVE? WHAT ARE THE KEY COMPONENTS THAT SHOULD BE INCLUDED IN A FALLS PREVENTION INTERVENTION? ARE MULTIFACTORIAL APPROACHES MORE EFFECTIVE THAN SINGLE INTERVENTION APPROACHES?

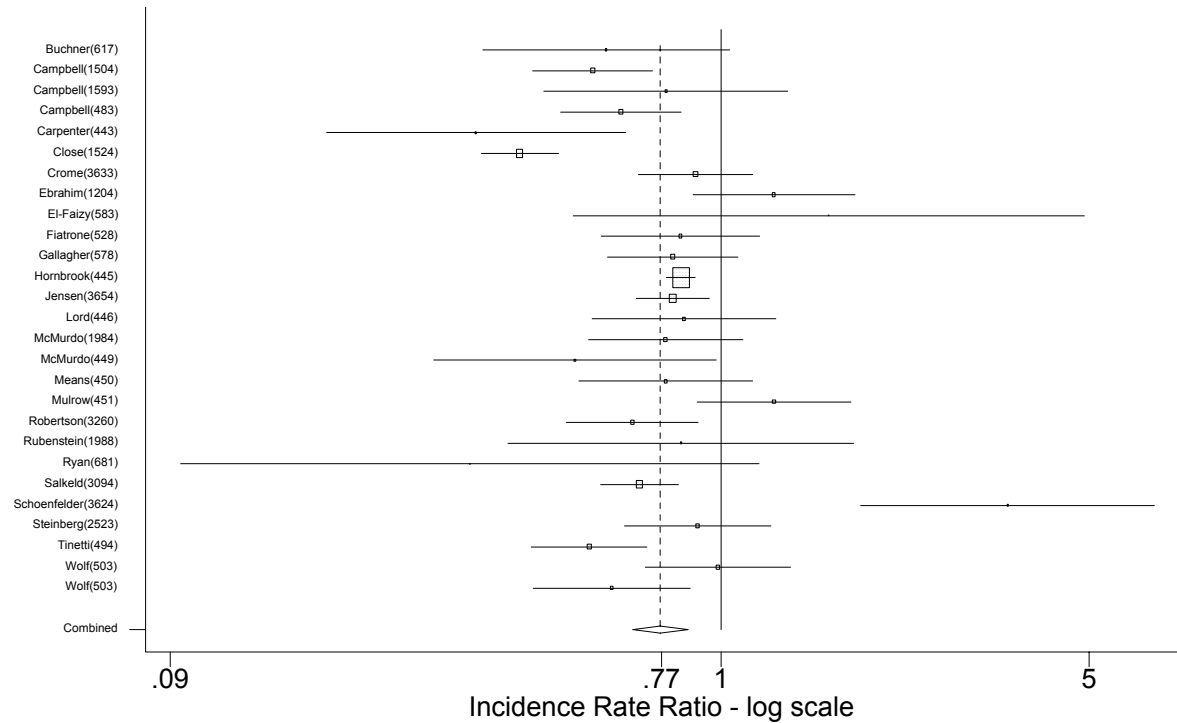
We performed meta-analyses on two clinically relevant outcomes: subjects who fell at least once and monthly rate of falling. The first meta-analysis included data from 22 treatment arms in 20 studies. The pooled risk ratio was calculated to determine whether combined studies would be associated with a reduced risk of falling, within a clinically comparable follow-up period – six to 18 months as described in the methods. The pooled risk ratio is 0.89, 95% CI [0.81, 0.98] indicating that the interventions in these studies are associated with a significantly reduced risk of falling. This is graphically displayed in Figure 5.

Figure 5. Shrinkage Plot of Clinical Trials of Falls Prevention Interventions Assessing the Outcome "Subjects Who Fell at Least Once"



The second meta-analysis, for efficacy in reducing monthly rate of falling, included data from 26 treatment arms in 27 studies which are displayed in the shrinkage plot below. The pooled incidence rate ratio is 0.77, 95% CI [0.68, 0.87] indicating that the interventions in these studies are associated with a significantly reduced number of falls, as displayed in Figure 6.

Figure 6. Shrinkage Plot of Clinical Trials of Falls Prevention Interventions Assessing the Outcome "Monthly rate of falling"



Area of the box is proportional to the variance.
Line represents 95% confidence intervals

Treatment Components

To investigate the effects of the differing intervention components of each of the treatment arms, detailed information about the type(s), intensity, exercise components, and setting of the interventions was obtained. The pooled risk ratio of studies that included a multifactorial falls risk assessment and management program was 0.84, 95% CI [0.73, 0.97] for risk of falling, while the pooled incidence rate ratio was 0.65, 95% CI [0.49, 0.85] for the number of falls. Similarly, when pooling studies that included an exercise intervention, we find that this subgroup of studies is significantly associated with a reduced risk of falling (adjusted risk ratio: 0.88, 95% CI [0.78, 1.00]) and with reduced number of falls (adjusted incidence rate ratio: 0.81, 95% CI [0.72, 0.92]). Four studies had both types of interventions and were included in both sub-analyses of intervention type.

Table 7. Pooled Analyses

| Study Type | Subjects who fell at least once | | | Monthly rate of falling | | |
|---|---------------------------------|----------------|------------------------------|-------------------------|----------------|---------------------------------------|
| | Number of Studies | Number of Arms | Adjusted Risk Ratio (95% CI) | Number of Studies | Number of Arms | Adjusted Incident Rate Ratio (95% CI) |
| All Studies Combined | 20 | 22 | 0.89 (0.81, 0.98) | 26 | 27 | 0.77 (0.68, 0.87) |
| Multifactorial falls risk assessment and management program | 10 | 10 | 0.84 (0.73, 0.97) | 7 | 7 | 0.65 (0.49, 0.85) |
| Exercise Only | 12 | 13 | 0.88 (0.78, 1.00) | 19 | 20 | 0.81 (0.72, 0.92) |

We did not find any studies that directly assessed the relative effectiveness of intervention components by comparing them head to head in a clinical trial (for example, trials comparing environmental modifications with exercise interventions). Therefore, our assessment of the relative effectiveness of intervention components used indirect methods, by comparing the magnitude of the effect of each independent component to a control group that received usual care. To assess the relative effectiveness of intervention components, we entered all such studies in meta-regression models that assess the effect of individual intervention components while controlling for other intervention components and study level differences. The results of the analyses are presented in Table 8. A multifactorial falls risk assessment and management program had a statistically significant beneficial effect in both analyses, and is probably the most effective intervention component in reducing both fall outcome measures. Exercise was an intervention component in the largest number of studies in both analyses. The pooled result favored exercise in reducing both the risk of falls and the rate of falls, although the results did not quite reach conventional levels of statistical significance. The balance of evidence supports exercise as the second most effective intervention component. Environmental modifications were the principal component of a small number of studies,

and the pooled estimate of effect was beneficial but not statistically significant. Education also was studied in only a small number of studies, and the pooled result was not statistically significant for either outcome. However, the 95% confidence intervals for the estimate are very wide and these results neither support nor refute the use of education as an effective individual intervention component.

We were not able to directly test whether multifactorial interventions were superior to single factor interventions, due to a paucity of single factor studies identified. However, an indirect argument favoring multifactorial interventions can be made since the most effective intervention, a multifactorial falls risk assessment and management program, is usually multifactorial.

The risk assessments included in multifactorial risk assessment varied among studies. Table 9 lists the included studies and the risks they assessed. The most commonly assessed risks were medication review, vision, environmental hazards, and orthostatic blood pressure

Table 8. Meta-regression Estimates of the Effect of Individual Intervention Components

| Treatment Component | Subjects who fell at least once | | Monthly rate of falling | |
|---|--|-------------------------------------|---------------------------------|--|
| | Number of Studies (Arms) | Adjusted Risk Ratio (95% CI) | Number of Studies (Arms) | Adjusted Incident Rate Ratio (95% CI) |
| Multifactorial falls risk assessment and management program | 10 (10) | 0.80 (0.68, 0.95) | 7 (7) | 0.60 (0.44, 0.82) |
| Exercise | 12 (13) | 0.87 (0.73, 1.04) | 19(20) | 0.84 (0.70, 1.01) |
| Environmental Modifications | 2 (2) | 0.95 (0.72, 1.25) | 3 (3) | 0.77 (0.49, 1.21) |
| Education | 2 (3) | 1.25 (0.91, 1.73) | 1 (1) | 0.33 (0.08, 1.35) |

Table 9. Components of a Multifactorial Falls Risk Assessment

| Study | Orthostatic BP | Vision | Balance & gait | Med Review | IADL/ ADL | Cognitive Evaluation | Environmental Hazards | Other |
|--------------|-------------------------------|---------------|---------------------------|-------------------|------------------|-----------------------------|------------------------------|--|
| 104 | | | | | X | | | |
| 105 | X | X | X | X | X | X | X | Hearing, depression assessment |
| 106 | X | X | X | X | | | X | Neuro & Musculoskeletal exam, lab tests, Holter |
| 16 | X | | X | X | | | X | Muscle strength and range of motion |
| 107 | | X | | X | | | X | Hearing, alcohol abuse assessment, assessment of physical activity |
| 108 | X | X | X | X | X | X | X | Health problems list |
| 31 | | | | X | | | | Self management skills, health assessment |
| 109 | X | X | X | X | X | X | X | Affect, carotid sinus studies (where clinical suspicion is high) |
| 110 | X | X | | X | | | | Review of lighting |
| 111 | | | | X | X | X | X | Physical health, psychosocial functioning |
| 33 | X | X | | X | | | | Review of lighting |
| 112 | No specific components stated | | | | | | | |
| 34 | | X | X | X | X | X | X | Hearing, review of lighting, review/repair assistive devices |

Among exercise interventions, we were not able to detect statistically significant differences in the efficacy between different types of exercises, although only endurance exercise individually achieved a significant effect in our analysis on subjects who fell at least once, while only balance exercise individually achieved a significant effect in our analysis on monthly rate of falling. There emerged no clear pattern and no conclusive evidence from these data to recommend particular exercises for falls prevention. Results are displayed in Table 10.

Table 10. Exercise Components

| Exercise Type | Subjects who fell at least once | | Monthly rate of falling | |
|---------------|---------------------------------|------------------------------|--------------------------|---------------------------------------|
| | Number of Studies (Arms) | Adjusted Risk Ratio (95% CI) | Number of Studies (Arms) | Adjusted Incident Rate Ratio (95% CI) |
| Balance | 7 (8) | 1.22 (0.64, 2.33) | 14 (15) | 0.76 (0.57, 1.01) |
| Endurance | 7 (7) | 0.89 (0.69, 1.15) | 5 (5) | 1.63 (1.06, 2.50) |
| Flexibility | 4 (4) | 0.90 (0.51, 1.59) | 5 (5) | 1.00 (0.63, 1.58) |
| Strength | 8 (9) | 0.82 (0.43, 1.56) | 14 (14) | 1.02 (0.73, 1.45) |

We assessed the effect of the intensity of intervention on efficacy. In our analysis on subjects who fell at least once, low intensity interventions were not effective, while medium or high intensity interventions were effective. Our analysis on monthly rate of falling showed no difference in effectiveness by intensity.

PUBLICATION BIAS

We assessed the possibility of publication bias for the risk ratio of falling at least once and for the falls incident rate for all studies included in the meta-analyses. Neither the adjusted rank correlation test ($p=0.26$, $p=0.92$), nor the regression asymmetry test ($p=0.06$, $p=0.79$) indicated publication bias. A visual inspection of the funnel plots (Figure 7 and Figure 8) confirmed this conclusion.

Figure 7. Funnel plot of studies assessing risk of falling at least once

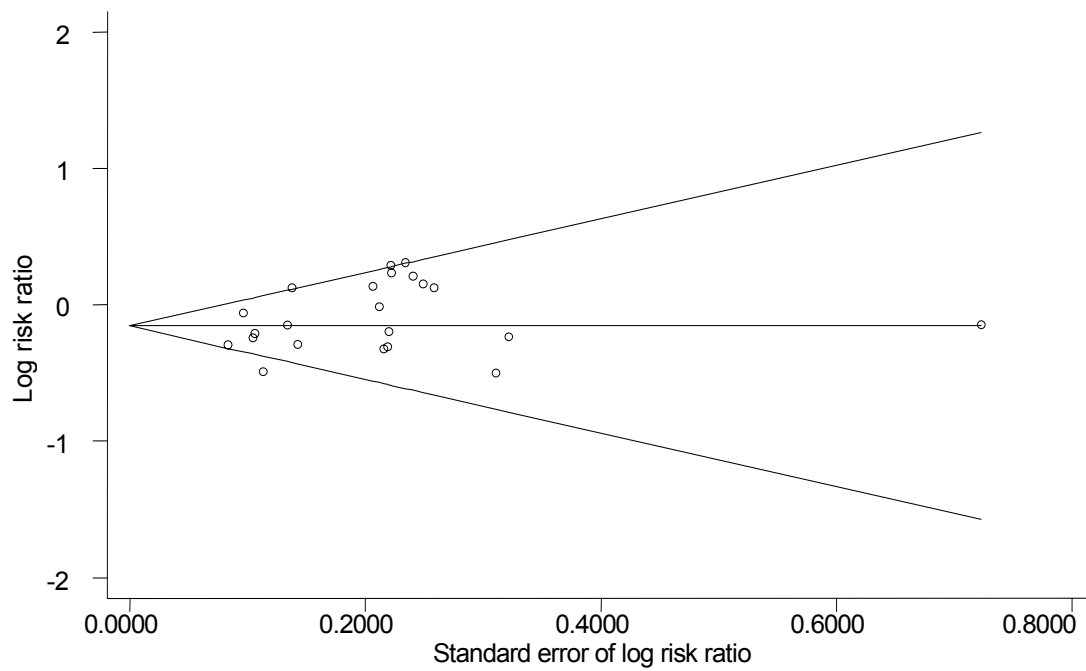
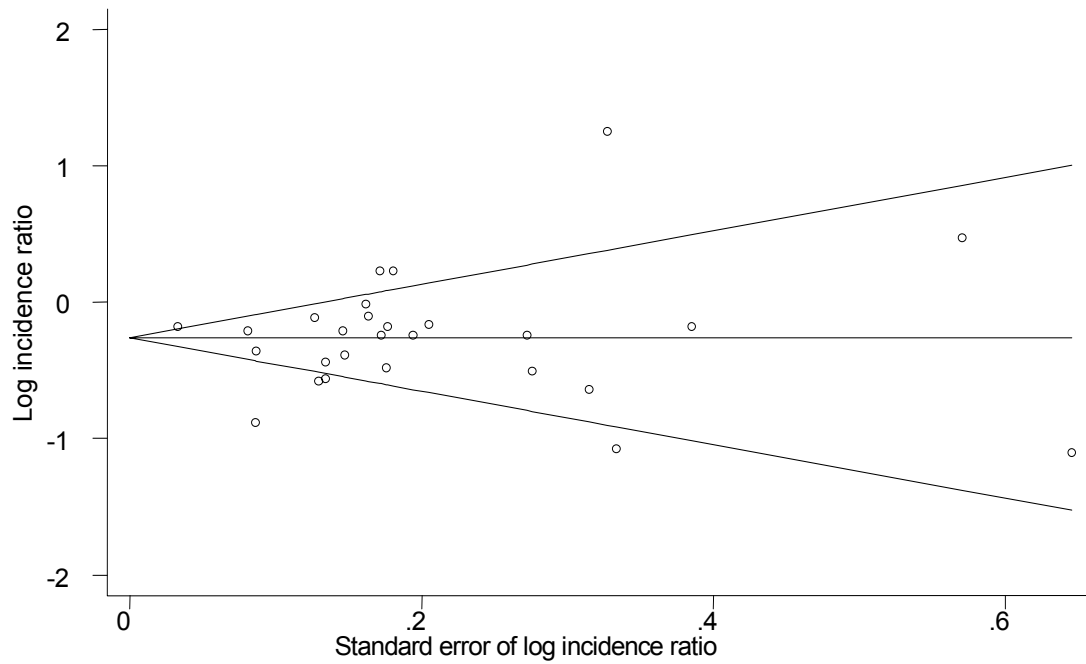


Figure 8. Funnel plot of studies assessing rate of falls



Preventing Injuries Resulting from Falls

In addition to interventions that seek to prevent falls, there are also interventions that seek to prevent injuries from falls rather than prevent falls themselves. Several recent articles have reported promising results.

The strongest evidence for preventing injuries comes from the large-scale randomized study on the use of external hip protectors by Kannus et al.⁹¹ A total of 653 elderly subjects with multiple falls risk factors were randomized to the hip-protector group, and 1,148 were assigned to the control group. The study showed the rate of hip fracture to be lower in the intervention group than in the control group (21.3 vs. 46.0 per 1,000 person years, respectively; relative hazard in the hip protector group: 0.4, 95% CI [0.2, 0.8] $P=0.008$). In the intervention group, the rate of hip fracture per fall was 84% lower among hip protector users than non-users (relative hazard: 0.2, 95% CI [0.05, 0.5] $P=0.002$).

Lauritzen and colleagues¹¹³ had previously conducted a randomized trial of hip protectors among Copenhagen nursing homes. The relative risk of hip fractures among residents in the intervention group was 0.44, 95% CI [0.21, 0.94]. While eight of the residents in the intervention group had a hip fracture, none of these were wearing the device at the time of the fracture.

A randomized study by Cameron and colleagues studied the effect of the use of hip protectors and contact with a nurse who promoted adherence on a subject's fear of falling and falls self-efficacy.⁷⁰ Subjects were elderly women with risk factors for falls who were randomized to an intervention group ($N=61$) and to a control group ($N=71$). At the 4-month follow-up, fear of falling was expressed by 43% of the subjects using the hip protector compared to 57% in the control group ($\chi^2=2.58$, $P=0.11$). Also, the subjects using the hip protector had greater improvement in falls self-efficacy as measured by the *Falls Efficacy Scale* ($t=2.44$, $P=0.16$), and the *Modified Falls Efficacy Scale* ($t=2.08$, $P=0.039$).

We also identified one study on a device for the prevention of injuries and cost. Zacker and colleagues,¹¹⁴ conducted an economic evaluation of an energy-absorbing flooring for the prevention of hip fractures compared to regular flooring. The study showed a payback period of 10.5 years when evaluating direct costs only, and a period of just over 11 months when evaluating both direct and indirect costs. The estimated cost-effectiveness ratios were less than \$1 per hip fracture prevented and life-year saved.

QUESTION 2. ARE PUBLIC INFORMATION OR EDUCATION CAMPAIGNS ALONE EFFECTIVE IN REDUCING OR PREVENTING FALLS?

We found no specific studies about the effectiveness of public information or mass education campaigns. In the meta-regression analyses, patient education given as part of multifactorial falls prevention programs did not show a significant independent effect.

QUESTION 3. WHICH CARE SETTINGS/ APPROACHES HAVE BEEN MORE EFFECTIVE FOR THE DELIVERY OF FALLS PREVENTION INTERVENTIONS? WHICH PROVIDERS SHOULD DELIVER THIS SERVICE?

Successful examples of falls prevention programs have been identified using a variety of approaches in a variety of settings. For example, Close¹⁰⁹ and Rubenstein¹⁰⁶ in the medical care system and Wagner¹⁰⁷ and Buchner¹⁷ in the population-based public health model obtained beneficial results.

Providers

Falls prevention interventions have been delivered by many different types of providers. Interestingly, physicians have rarely been the sole provider type. Successful falls prevention interventions have been provided by fitness instructors, nurses, physical therapists, social workers, and teams of multiple providers. The evidence is currently not sufficient to conclude that any one provider type is preferable over another. Our exploratory analysis revealed a poor distribution of provider types, which left us unable to perform a pooled analysis on this topic.

Care Settings

Falls prevention interventions have been carried out in a variety of settings. Successful interventions have been conducted in physician offices, patient homes, hospitals, nursing homes, community centers, and specialized research centers. No evidence currently exists to advocate for increased effectiveness based on care setting. Our meta-regression of setting (Table 11) did not show statistically significant differences in efficacy between setting types.

Table 11. Setting Types

| Setting Type | Subjects Who Fell at Least Once | | Monthly rate of falling | |
|---------------|---------------------------------|------------------------------|--------------------------|---------------------------------------|
| | Number of Studies (Arms) | Adjusted Risk Ratio (95% CI) | Number of Studies (Arms) | Adjusted Incident Rate Ratio (95% CI) |
| Medical | 7 (7) | 0.90 (0.76, 1.05) | 9 (9) | 0.85 (0.66, 1.09) |
| Non-Medical | 7 (9) | 0.95 (0.80, 1.12) | 7 (7) | 0.69 (0.54, 0.87) |
| Not Described | 6 (6) | 0.80 (0.65, 0.99) | 9 (10) | 0.81 (0.64, 1.03) |

QUESTION 4. WHAT ARE THE KEY ISSUES IN SUSTAINING FALLS PREVENTION PROGRAMS?

Two key issues are involved in sustaining falls prevention programs: obtaining and maintaining sufficient funding and availability of programs. The interventions reviewed in this report were performed through the use of special funding from research grants or demonstration projects, and none of them continued as regular programs. Funding clearly seems to be needed to sustain falls prevention programs and would be required to bring about the widespread use of effective interventions.

QUESTION 5. COST EFFECTIVENESS OR COST SAVINGS: DO FALLS PREVENTION INTERVENTIONS APPEAR TO REDUCE HEALTH CARE COSTS BY REDUCING DISEASE, PHYSICIAN OFFICE VISITS, HOSPITALIZATIONS, NURSING HOME ADMISSIONS, ETC.?

The high incidence of falls among people 65 and older and the substantial associated costs constitute a major problem (see Introduction). The growing elderly population exacerbates the problem in the United States and most other countries. For instance, annual Medicare costs for hip fractures are projected to increase from \$2.9 billion in 1991¹⁰ to \$240 billion by the year 2040.¹¹ Thus, one of the questions of interest is whether the provision of falls prevention interventions reduces health care costs, and if so, how (e.g. by reducing injuries, physician office visits, hospitalizations, nursing home admissions)? In this section, we review the evidence presented by 15 studies (16 publications) regarding the cost-effectiveness or cost-savings of falls prevention interventions. We first summarize the overall findings, irrespective of type of intervention. Then we discuss the findings by type of intervention. One must keep in mind that cost effectiveness is discussed only in a small portion of published studies; thus, we did not limit this section to controlled trials.

Overall cost-effectiveness of falls prevention interventions

Among the 15 studies of cost-effectiveness reviewed, six studies utilized multifactorial interventions,^{16, 35, 78, 105, 106, 108, 109} and nine studies implemented a single intervention. These include four studies using specific physical activity or exercise programs;^{17, 99, 115, 116} three focused on environmental modification (including two simulation-based modeling studies);^{114, 117, 118} one study using practice redesign by chronic care clinics;³¹ and one study using patient reminders.¹¹⁹ Three of the 15 studies were intended to improve overall health and functional status for the elderly, where falls prevention was just one domain of the measured outcomes.^{31, 99, 105} The rest of the studies are focused exclusively on falls prevention and fall-related injury reduction for the elderly. Most studies recruited community-living seniors, except for two that focused on nursing home residents,^{99, 106} one that used simulated nursing home residents,¹¹⁴ and one study of rehabilitation hospital patients.¹¹⁹ A summary of the 15 studies is presented in Table 12. Although all the studies provided information on health care costs or utilization, only eight of the studies, including the two simulation studies, reported information on the costs of the intervention.^{78, 99, 106, 114-118}

Table 12. Cost Effectiveness Articles

| Type of intervention | Author, Year | Subjects | Settings Research design Follow-up period Control | Costs of intervention Effectiveness Health care costs or utilizations | C/E Ratings |
|--|---------------------------------------|--|--|---|---|
| Risk factor identification (physical, functional, and medication examination) Tailored multifactorial prevention program (combination of medication adjustment, behavioral recommendations, and exercises, as determined by participants' baseline assessment.) | Tinetti , 1994 and Rizzo , 1996 | 301 men and women >= 70 years old (mean = 78) who had at least one of eight targeted risk factors for falling (153 = TI; 148 = CT) | Patient's home RCT 1 year Home visits from social work students | \$905 (range \$588 to \$1346, 1993 dollars) per targeted intervention participant. Assumed no cost to the control group. Mean intervention costs per fall prevented = \$2150 | Cost effective. Maybe cost saving. |
| | | | | Significant reduction in the risk of falling. The proportion of persons with the targeted risk factors for falling was reduced. | |
| | | | | Mean health care costs were \$2000 less in the intervention than control group, but median costs were \$1100 higher in the intervention than control group. The intervention strategy showed its strongest effect among individuals at high risk of falling | |
| Risk factor identification (physical examination and environmental assessment) Tailored preventive & therapeutic recommendations | Rubenstein , 1990 | Within 7 days of a fall, 160 ambulatory nursing home patients (mean = 87 years old) were randomly assigned to receive either a postfall assessment (n = 79) or usual care (n = 81) | A nursing home RCT 2 years Usual care | Less than \$300 (1989 dollars) per pt for the costs of a 1-hour standardized assessment of institutionalized fallers done by a nurse practitioner followed by recommended interventions | Cost effective and cost saving. |
| | | | | Through the use of the assessment, many remediable problems were detected. Int. pts had 9% fewer falls (NS) and 17% fewer deaths (NS). | |
| | | | | At the end of the 2-year period, the int. group had 26% fewer hospitalizations (p <.05) and a 52% reduction in hospital days (p <.01). Such reduced hospitalizations are estimated to save more than \$800 annually per institutionalized faller. | |
| A structured detailed medical, functional, and environmental assessment with individual counseling about safety and home modifications and referral to relevant services if indicated | Close, 1999 | 397 community-living patients 65 years and older (mean = 78) who presented to an accident and emergency department with a fall (213 in control and 184 in intervention group) | Hospital and patient's home RCT 1 year Usual care | Not available | Insufficient information |
| | | | | At 12-month follow-up, the intervention group reported 183 falls, whereas the control group reported 510 falls. The risk of falling was significantly reduced in the intervention group (odds ratio 0.39). The decline in functional status with time was greater in the control group. | |
| | | | | The odds of at least one hospital admission were lower in the intervention group (0.61 [0.35-1.05]). | |
| A comprehensive intrinsic and extrinsic risk assessment, individualized feedback about identified risks, and a motivational video and booklet | Gallagher, 1996 | 100 community-living persons 60 years and older (mean = 75 years) (50 in intervention group and 50 in control group) who had | Patient's home RCT 6 months Usual care | Not available | Insufficient information (implied not cost effective) |
| | | | | No statistically significant differences between the intervention and control groups on the outcome measures including fall incidence, falls self-efficacy, fear of falling, social functioning, and quality of life. | |

Table 12. Cost Effectiveness Articles (continued)

| Type of intervention | Author, Year | Subjects | Settings Research design Follow-up period Control | Costs of intervention Effectiveness Health care costs or utilizations | C/E Ratings |
|--|-------------------|--|--|--|---|
| | | experienced a fall in the preceding three months | | No statistically significant differences between the intervention and control groups in health service utilization, which was determined by a 15-item scale itemizing local health services that are available for the elderly. | |
| Home safety hazards assessment and modification recommendations and assistance. Non-tailored health behavior interventions consisted of group meetings led by a health behaviorist and a physical therapist to address fall risks and included exercise component | Hornbrook, 1994 | 3182 independently living persons aged 65 years and older (mean = 73) who were members of a group-model HMO (intervention = 1611; control = 1571) | Patient's home RCT 2 years Home assessment. Informed about potential home - safety hazards and given a safety booklet | Not available | Insufficient information (implied not cost saving) |
| | | | | Only marginal success in reducing falls. The intervention decreased the odds of falling by 0.85, but reduced the average number of falls among those who fell by only 7%. The effect was strongest among men age 75 and older. | |
| | | | | The intervention program had no significant effects on the probability of medical care falls or the number of medical care falls among fallers. Neither did the effects on fracture falls. The intervention did not have significant effects on the probability of being hospitalized as a result of a fall or on the number of hospitalized falls. | |
| In-home geriatric assessments to screen for medical, functional, psychosocial and home hazards problems, followed by a letter describing findings and recommendations and follow-up visits by trained volunteers at 4-month intervals for 1 year. The goal is to provide preventive health care and improved health and functional status. | Fabacher, 1994 | 254 community-living veterans, 70 years and older, not currently receiving health care at the Sepulveda VA Medical Center (131 intervention; 123 controls) | Patient's home RCT 1 year Usual care | Not reported in dollar values. Available information includes 183 hours of physician's assistant or nurse time and 600 hours of volunteers' time in home visits. 20 hours of volunteer training program. | Insufficient information |
| | | | | Home modification to reduce risk for falls was recommended to 28 subjects (out of 385 recommendations). Self-reported fall rates were not significantly different between the groups; however, there was a trend toward fewer intervention subjects falling during the follow-up year (14% vs. 23%, $p = 0.10$). Intervention subjects had better functional status scores than controls. | |
| | | | | Non-prescription drug use increased significantly among controls, but not among intervention subjects. The percent of subjects hospitalized in the follow-up year was similar in the two groups. No subject in either group was admitted to a nursing home. | |
| Individually prescribed home-based exercise program | Robertson , 2001a | 240 women and men aged 75 years and older (mean = 81). Exercise group = 121 and control | Patient's home RCT 1 year Usual care | The program costs \$NZ432 (at 1998 dollars) per person to deliver, or \$NZ1803 per fall prevented. \$NZ155 per fall prevented when hospital costs averted were considered. | Cost effective. Cost saving for those age 80 years and older. |

Table 12. Cost Effectiveness Articles (continued)

| Type of intervention | Author, Year | Subjects | Settings Research design Follow-up period Control | Costs of intervention Effectiveness Health care costs or utilizations | C/E Ratings |
|---|------------------|---|--|--|-------------------------------------|
| | | group = 119 | | 46% reduction in the number of falls for the exercise group. The number of falls was significantly reduced in those aged 80 years and older, but no difference was found in participants ages 75 to 79 years. Five hospital admissions were due to injuries caused by falls in the control group and none in the exercise group. The program resulted in cost savings of \$NZ576 per fall event prevented and \$NZ1563 per injuries fall event prevented for those age 80 years and older. | |
| Individually prescribed home-based exercise program | Robertson, 2001b | 450 women and men aged 80 years and older (mean = 84). Exercise group = 330 and control group = 120. | Patient's home CCT 1 year Usual care | The program costs \$NZ418 (at 1998 dollars) per person to deliver, or \$NZ1519 (£441) per fall prevented. 30% reduction in the number of falls. Fewer participants had falls resulting in injuries, but there was no difference in the number who had serious injuries. No difference in hospital costs resulting from falls. The difference in the actual costs of hospital admissions between participants from the exercise and control group as a results of a fall was not significant. | Cost effective but not cost saving. |
| Individually tailored one-on-one physical therapy sessions three times a week for 4 months. | Mulrow, 1994 | 194 (97 in each group) nursing home residents older than 60 years (mean=81), dependent in at least two activities of daily living, residing in the nursing home for at least 3 months | Nursing homes RCT 4 months Friendly visits three times a week for 4 months. | Charge for the 4-month physical therapy program was \$1220 (1993 dollars) per subject. For friendly visits program was \$189 per subject. Compared with the FV group, the PT group experienced NO significant improvements in overall Physical Disability Index, Sickness Impact Profile, or activities of daily living scores. PT used fewer assistive devices. 79 falls in PT vs. 60 falls in FV. Health care charges did not differ significantly between PT and FV groups. | Not cost effective. |
| Supervised strength and endurance training | Buchner , 1997 | 105 adults, age 68-85 years old, (mean = 75) with at least mild deficits in strength and balance were selected from a random sample | Community classes RCT 18 months Usual activity | Not available Exercise had a protective effect on risk of falling (relative hazard = 0.53, C.I. = .30 -.91). 42% of exercise subjects reported a fall compared to 60% of control subjects. No effects of exercise on gait, balance, or physical health status. | Insufficient information |

Table 12. Cost Effectiveness Articles (continued)

| Type of intervention | Author, Year | Subjects | Settings Research design Follow-up period Control | Costs of intervention Effectiveness Health care costs or utilizations | C/E Ratings |
|-----------------------------------|--------------------------|---|---|--|---|
| | | of enrollees in a HMO | | Between 7 and 18 months after randomization, control subjects had more outpatient clinic visits although there were no significant differences between groups in ancillary outpatient costs. Hospital use was similar in both groups. However, hospitalized controls were significantly more likely to spend more than 3 days in the hospital and sustain hospital costs over \$5000 ($p < .05$) | |
| Home assessment and modifications | Salkeld , 1999 | 530 subjects age 65 years and older (mean=77) recruited mostly during a hospital stay. Intervention group = 264, and control group = 266. | Patient's home RCT 1 year Usual care | Occupational therapist intervention costs = \$116 (1997 Australian dollars) and home modification costs = \$7. Mean intervention costs per fall prevented = \$129 | Cost effective. Maybe cost saving for subjects who have falls history in the previous year. |
| | | | | 226 falls in the intervention group and 324 falls in the control group. The reduction in falls was significant in the subgroup of people who had a falls history, but insignificant among subjects without falls history. | |
| | | | | The intervention led to increased overall health care costs (mean = \$1805). The average cost per fall prevented was \$4986. A sensitivity analysis was conducted by removing 15 outlier subjects. The average cost per fall prevented was \$1921 for all intervention subjects and was cost saving for subjects who had falls history. | |
| Home assessment and modifications | Smith & Widiatmoko, 1998 | 75 years or over, living independently in the community | N/A Simulation-based decision-analytic model 1 year and 10 years No intervention | The average cost of the intervention per person was estimated to be \$190 (1996 Australian dollars). | Indicative of cost saving under assumed effectiveness |
| | | | | It was assumed the fall rate = 0.4 and injury rate after a fall = 0.1 with no intervention. It was assumed that the intervention would reduce the fall rate over any one-year period by 25%. | |
| | | | | It was estimated on average \$71.68 would be spent on fall-related treatment per elderly person with no intervention, and decreasing to \$53.76 following intervention. Over a one-year period, incremental costs of introducing the intervention = \$172 per person. Cost per fall prevented = \$1721, and cost per injury prevented = \$17208. Over a 10-year period, the intervention resulted in a cost saving of \$92 per person. | |
| Practice redesign – | Coleman , 1999 | 169 patients ages 65 | Nine primary care | Not available | Insufficient |

Table 12. Cost Effectiveness Articles (continued)

| Type of intervention | Author, Year | Subjects | Settings Research design Follow-up period Control | Costs of intervention Effectiveness Health care costs or utilizations | C/E Ratings |
|--|---------------------|--|---|---|---|
| Chronic care clinics (disease management planning, medication review, patient self-management/support group) | | and older (mean = 77) with the highest risk for being hospitalized or experiencing functional decline (Intervention group = 5 physicians, and 96 patients, and control group = 4 physicians and 73 patients) | physician offices in a large staff-model HMO RCT 2 years Usual care | <p>After 24 months, no significant improvements in frequency of incontinence, proportion with falls, depression scores, physical function scores, or prescriptions of high-risk medications were demonstrated. A higher proportion of intervention patients rated the overall quality of their medical care as excellent than did control patients (40% vs. 25%, $p = 0.1$)</p> <p>Costs of medical care including frequency of hospitalization, hospital days, emergency and ambulatory visits, and total costs of care were not significantly different between intervention and control groups.</p> | information |
| Energy-absorbing flooring in nursing home | Zacker & Shea, 1998 | 8 nursing home residents who will experience at least five falls per year and are at greatest risk of fracturing a hip. | Atypical 200-bed nursing home Simulation-based decision-analytic model 40 years Traditional floors | <p>The total 40-year costs of the flooring intervention are estimated to be \$75,391(1995 dollars)</p> <p>The probability of hip fracture from fall was assumed to be 2% without safety floor and 1% with safety floor, yielding an estimated 6.86 hip fractures prevented and 15.44 life-years saved over 40 years.</p> <p>The total 40-year direct medical costs avoided were estimated to be \$123,545. When adding indirect morbidity and mortality avoided, the total benefits of the flooring intervention were estimated to be \$1, 247,876. Cost effectiveness ratios of less than \$0 per hip fracture prevented and life-year saved were estimated.</p> | Indicative of cost saving under assumed effectiveness |
| Identification bracelets as a reminder to prevent falls | Mayo, 1994 | 134 high-risk patients (mean age = 72) who are undergoing in-patient physical rehabilitation (65 with bracelet and 69 with no bracelet) | A rehabilitation hospital RCT From admission to discharge Patients were told to remember to be careful | <p>Not available</p> <p>The persons with the identification bracelet had a higher probability of falling (a hazard ratio of 1.3). There were no differences between the two groups on location of fall or its severity, functional status, time-to-first-fall, and frequency of falling</p> <p>There was no significant difference between the two groups on length of stay (75.5 days for intervention group and 67.2 days for control group).</p> | Insufficient information (implied not cost effective) |

Of the 13 clinical trials, six studies reported a significant reduction in the risk of falling (at $\alpha = .05$ level),^{16, 17, 106, 109, 115, 116} three studies found a marginal reduction,^{35, 105, 117} and four studies did not find such an effect.^{31, 99, 108, 119} Among the six studies that reported significant effects in reducing the risk of falling, one reported significantly fewer hospitalizations and a reduction in hospital days in the intervention group compared to the control patients¹⁰⁶ (the subjects in this study had fallen in the week prior to having been recruited for the study). Three other studies also found cost saving potentials for high-risk elderly although not for all study subjects.^{78, 115, 117}

Utilization of health care services was measured in two studies

One study reported that the odds of at least one hospital admission were lower in the intervention group than the control group.¹⁰⁹ Another study found fewer outpatient clinic visits among intervention subjects than control subjects, and the intervention group was significantly less likely to spend more than three days in the hospital and to sustain hospital costs over \$5000 than controls.¹⁷ However, these two studies did not report the costs of interventions, so we cannot compare their cost-effectiveness with other studies, nor can we judge their cost savings compared to usual care.

One study that reported a significant reduction in the risk of falling also found that fewer intervention participants had falls resulting in injuries, compared to control patients.¹¹⁶ However, since there was no difference in the two groups in terms of serious injuries, and the distribution of hospital cost data was highly skewed, this study did not find savings in hospital costs resulting from reduced falls. The remainder of the six RCT studies that found either marginal or no effects on falls prevention correspondingly found no significant reduction in health care costs or utilization.^{31, 35, 99, 105, 108, 119}

The results of the two simulation-based studies^{114, 118} suggested that cost savings would result from most interventions that were assumed to be effective. Even in the worst-case estimates, Zacker and Shea¹¹⁴ reported that the cost per life-year saved by preventing hip fractures compared very favorably with other injury-prevention interventions.

Cost-effectiveness review by type of falls prevention intervention

Although we identified studies of five types of interventions that included costs or health care utilization information, available evidence on two of them did not warrant a detailed discussion. Mayo and colleagues¹¹⁹ concluded that using identification bracelets as a reminder was of no benefit in preventing falls among high-risk hospitalized patients. Coleman and colleagues³¹ also did not find beneficial effects of practice redesign by implementing chronic-care clinics on falls prevention. Thus, although program costs were not reported in these two studies, these two types of interventions do not appear to be cost effective or cost saving. As for the other types of intervention – multifactorial, exercise alone, and environmental modification alone – they are discussed in greater detail below. However, the available evidence does not support a conclusion regarding which type of falls prevention intervention is most cost effective, because of the heterogeneity among studies and inadequate quality of the cost-effectiveness analyses.

Multifactorial Interventions. All six multifactorial interventions involved risk-factor identification and tailored multifactorial prevention program or recommendations, except

for one that utilized non-tailored group meetings.³⁵ However, only three of the six studies showed reductions in healthcare costs or utilization.^{78, 106, 109} Close and colleagues¹⁰⁹ did not provide cost data, so we could not assess the economic impact of that study.

Two studies reported both costs of interventions and health care costs or utilization outcomes. Rizzo and colleagues⁷⁸ conducted a detailed economic evaluation of a home-based multifactorial intervention. The authors compared the mean health care costs of the intervention group with those of the control group, in particular among high-risk individuals. However, a few control subjects incurred very costly hospitalizations; thus, the median cost may be more a representative measure of central tendency in such cases. If one compares median health care costs between the two groups, total health care costs were higher in the intervention group as well as in high-risk subgroups than in controls.

Rubenstein and coworkers¹⁰⁶ did not intend to conduct a formal cost-benefit analysis, but their rough estimation was that the costs of intervention averaged less than \$300 (in 1989 dollars), while the savings averaged more than \$800 annually per nursing-home faller. We cannot determine from these numbers whether the intervention is cost saving, because this report did not use a consistent perspective in costing (program vs. societal). The costing method which resulted in the omission of costs that were beyond the program implementation (from the societal perspective) and/or overestimation of the health care cost savings (from the program implementation perspective).

Specific Exercise. Four studies assessed the use of specific exercises to prevent falls. One study used an individually prescribed home-based exercise program that involved trained nurses for home visits and exercise prescription.^{115, 116} The second study implemented individually tailored one-on-one physical therapy sessions provided by physical therapists to nursing-home residents.⁹⁹ The third study involved supervised strength and endurance training in community classes to enrollees of an HMO.¹⁷

Robertson and colleagues¹¹⁵ studied 240 women and men aged 75 years and older and reported fewer hospitalizations because of fall-related injuries in the exercise group than in the control group. In addition, the authors reported that the individually prescribed exercise intervention was cost saving for those aged 80 years and older. However, when this intervention was replicated in a multicenter controlled trial, the reduction of the number of falls resulted in no difference in hospital costs.¹¹⁶ The authors discussed several possible reasons for the discrepancy in the results. One possible reason is that the low incidence of serious injurious falls in the study samples and the highly skewed hospital cost distribution make the findings of reduced health care costs unreliable.

Although the goal of the second study was to improve the function of very frail, long-term nursing home residents, the physical therapy program provided only modest mobility benefits.⁹⁹ Health care charges did not differ significantly, although the cost of delivering the physical therapy program was over \$1000 more per subject than was the cost of the control intervention (friendly visits).

The study of strength and endurance training¹⁷ reported fewer outpatient clinic visits in their intervention group than in the control group, but the reduction did not result in significant differences between groups in ancillary outpatient costs. Nevertheless, although hospital use was similar in both groups, the study did report that the hospitalized control subjects were likely to have a significantly longer length of stay and were significantly more likely to incur hospital costs over \$5000 than the intervention subjects. However, cost-effectiveness cannot be assessed for this study, because the cost of intervention was not reported.

Environmental Modification. Information regarding cost-effectiveness of environmental modification is available from one RCT and two simulation-based modeling studies.

The home hazard reduction program reported that the intervention led to increased health care costs, although there was a reduction in the number of falls.¹¹⁷ The program was more effective and had a better cost-effectiveness ratio among persons who had fallen in the previous year. In their sensitivity analysis, the authors removed 15 outliers from the analysis who either incurred total costs that were more than three standard deviations above the group mean or reported more than 50 falls in the study year. With the removal of the outliers, the authors found that the (mean or median) cost per fall prevented actually represented a cost saving among subjects who had fallen in the previous year. However, as the authors also noted, nearly all hospital admissions during the study period were unrelated to falls (similar to the findings of Rizzo and colleagues⁷⁸). Thus, the observed/apparent increase in health care costs was assumed to be a chance result.” Such a conclusion also challenges the validity of the cost-saving results found for the high-risk subjects in the sensitivity analysis.

The long-term benefits (or effects) of an environmental modification intervention are more predictable than those of multifactorial interventions or exercise programs. Hence, both the simulation-based studies investigated the cost-effectiveness of environmental modification interventions over the long term (10 years in Smith and Widiatmoko¹¹⁸ and 40 years in Zacker and Shea¹¹⁴), using available published literature. As we mentioned above, the two decision analytic models indicated the potential for considerable benefit to be gained from either a home assessment and modification program or the Penn State University Safety Floor, a type of energy-absorbing flooring. Smith and Widiatmoko¹¹⁸ showed that over a 10-year period, the study's home assessment and modification program resulted in a cost saving of \$92 per person (1996 Australian dollars). The study by Zacker and Shea¹¹⁴ “revealed a payback period of 10½ years if using only direct costs and just over 11 months when direct and indirect costs were included.” Actual clinical trials are needed to demonstrate the efficacy and cost-effectiveness of these falls-prevention strategies.

Conclusion from Published Literature

Whether a falls prevention intervention is cost effective or cost saving is a function of many parameters, including the targeted population, the environment where the targeted population resides, design and implementation, time, the accounting of benefits and costs, the perspective of costing, and the selection of a comparison group. The limited studies of cost-effectiveness include substantial heterogeneity in the above parameters. This

heterogeneity hinders us from comparing the relative cost-effectiveness by type of intervention and from drawing definitive conclusions about the economic impact of falls prevention interventions. In the preceding discussion, we also assessed the quality of the available studies in conducting their cost-effectiveness analysis. Common threats to the validity of cost-effectiveness analyses in the above studies include 1) the highly selective trial population (that results in “cost-efficacy” instead of “cost-effectiveness” findings, and unknown generalizability); 2) lack of a clear perspective in accounting for costs and benefits; and 3) inadequate sample size (which causes the health care cost and utilization outcomes to be influenced substantially by a few outliers).

Overall, the evidence is not conclusive but suggests that an effective intervention provided to people with a high risk of falling has the potential to be cost saving compared with current practice. An effective falls prevention intervention is also likely to result in more efficient resource allocation than many other types of prevention interventions (e.g., hypertension control interventions to prevent myocardial infarctions) for elderly people. Further research is needed to inform policy-makers about which intervention is effective for what population and should use sound methodology to provide more solid evidence for cost-effectiveness of falls prevention interventions.

Preliminary Cost-Effectiveness Analysis

We conducted a preliminary analysis on the economic impact to Medicare of providing a falls prevention rehabilitation benefit to Medicare beneficiaries age 65 and older who have just fallen. The findings presented in Tables 13-18 are based on published estimates of fall rates, medical costs, and population projections. They are also based on conservative estimates of risk reduction, penetration rate, and the share of medical costs borne by Medicare. This analysis uses our meta-analytic estimates of the effectiveness of falls prevention interventions.

Population Projection. We used data from the 2000 Census to estimate the number of eligible Medicare beneficiaries in 2002. Assuming 1% annual growth, there will be 18.66 million Medicare beneficiaries age 65 to 74, and 16.94 million beneficiaries age 75 and older in 2002.

Number of Falls with Injury. The most comprehensive study of slip and fall injuries among older adults is by Rice et al., 1989,¹²⁰ which was updated by Englander et al in 1996. Englander⁹ estimated the annual number of falls with injury was 6,215 per 100,000 population for persons age 65 to 74, and 10,932 per 100,000 for those age 75 and older. Multiplying these rates by the age-specific Medicare population in 2002 yields estimates of 1.16 million falls with injury among 65 to 74 year olds, and 1.85 million for Medicare beneficiaries age 75 and older in 2002.

Cost per Fall with Injury. Englander⁹ estimated the direct medical cost of a fall resulting in injury was \$6,215 in 1994 dollars. This estimate includes expenditures for hospital and nursing home care, physician and other professional services, rehabilitation, community-based services, drugs and medical equipment, insurance administration, and home modification. Inflating this figure at a 5% annual rate yields a direct cost of \$9,182 per

fall with injury in 2002 dollars. If we assume (conservatively) that Medicare pays 60% of direct medical costs of beneficiaries, then the total cost to Medicare associated with these falls is \$16.6 billion in 2002.

Risk Reduction. We used our meta-analysis to estimate the expected reduction in falls due to the proposed intervention. The pooled estimate of the independent effect of a multifactorial falls assessment and management program was a 40% reduction in falls of all types (with and without injury). We assume the same rate of reduction in falls from the falls prevention rehabilitation benefit, and that the effect is proportionate across fall types and will reduce the number of falls with injury by 40%.

Cost Estimates. We assume a falls prevention rehabilitation benefit will be available to 90% of seniors who suffer a fall, assuming the other 10% of seniors are too ill or frail for a rehabilitation program, or their fall results in death. Since it was estimated that 50% of all falls are recurrent falls^{3, 121, 122}, the expected number of falls with injuries should reduce by 542,000 (209,000 from age 65 to 74 years old; 333,000 from people 75 and older). The reduction of falls are from the assumed 30% of people age 65 to 74, and the 38% of people age 75 years and older who fall at least once in a given year.

We assume a falls prevention rehabilitation benefit will include a detailed evaluation by a specialist(s) for the 90% of previous fallers, of whom, 60% will go through a rehabilitation program. The others will only be given recommendations for behavioral, environmental, or medical modifications (e.g., change of medicine). Additionally, all of these people (i.e., 90% of previous fallers) will need at least 1 follow-up visit to ensure that fall prevention recommendations are being implemented.

In this modeling exercise, we assume CMS will reimburse the detailed evaluation at an average of \$95 (this will of course vary greatly depending on the particular type and number of specialist referrals necessary), \$280 for the rehabilitation program (\$35 per session for 8 paid sessions, 2/week for 2 weeks then 1/week for 4 weeks), and \$40 for the follow-up visit. Given such reimbursement rates, it is estimated that the falls prevention rehabilitation benefit will cost Medicare \$272 million in 2002. In return for this payment, the number of falls with injury is expected to decrease by 542,000. This results in an average cost to Medicare of about \$500 to prevent a fall with injury. The costs to Medicare vary by age, with a cost of \$376 million for persons aged group 65-74 and a savings of \$104 million for persons aged 75 and older (Table 13). Since Medicare only pays a portion of total direct costs (we assumed 60% in this analysis), the effect of the falls prevention rehabilitation program on total direct costs is even more advantageous. We estimate the proposed program would actually result in a net savings of \$1.7 billion when total direct health care costs are considered.

Sensitivity Analyses. To assess the robustness of our findings to underlying assumptions, we substituted more conservative estimates for five critical parameters. First, we lowered the share of direct medical costs borne by Medicare to 50%. Second, we assumed the intervention would reduce fall rates by only 18% (the lower bound of the 95% confidence interval) rather than the 40% estimate in our base case analysis. Third, we lowered the

penetration rate by assuming only 80% of older Medicare beneficiaries with a previous fall would receive the intervention in a given year. Fourth, we increased the percentage of Medicare beneficiaries who would need fall rehabilitation to 70%. Fifth, we raised the cost of fall rehabilitation to CMS from \$280 to \$350 per beneficiary.

Using more conservative estimates, the costs to Medicare become \$770, \$1,915, \$242, \$573, and \$724 million respectively, in each case of a more conservative assumption of parameters (Tables 14-18). However, given the large number of fall-related injuries prevented (542,000 in base case, and 244,000 in the lower bound case scenario), the falls prevention rehabilitation benefit can be considered a cost-effective intervention.

Table 13. Cost Analysis Base Case Estimation

| Baseline Estimation | Age 65-74 | Age 75 and older |
|--|-------------------|-------------------------|
| Population | 18,660,102 | 16,937,631 |
| Number of people fall | 5,598,030 (30%) | 6,351,612 (38%) |
| Number of fall injuries | 1,159,763 | 1,851,571 |
| Medicare cost per fall injury | \$5,509 | \$5,509 |
| Medicare cost for all fall injuries | \$6,389,632,621 | \$10,201,103,173 |
| Number of reduced falls with injury | 208,757 | 333,283 |
| Reduced Medicare cost | (\$1,150,133,872) | (\$1,836,198,571) |
| Intervention cost | \$ 1,526,582,913 | \$ 1,732,084,459 |
| Medicare cost for fall injuries after intervention | \$6,766,081,662 | \$10,096,989,060 |
| Cost (savings) to Medicare | 376,449,041 | (\$104,114,112) |

Table 14. Cost Analysis Sensitivity Analysis 1

Sensitivity Analysis 1: Medicare's share = 50% of direct cost of fall injuries

| Baseline Estimation | Age 65-74 | Age 75 and older |
|-------------------------------------|------------------|-------------------------|
| Medicare cost per fall injury | \$4591 | \$4591 |
| Medicare cost for all fall injuries | \$5,324,693,851 | \$8,500,919,311 |
| Reduced Medicare cost | (\$958,444,893) | (\$1,530,165,476) |
| Cost (savings) to Medicare | \$568,138,020 | \$201,918,983 |

Table 15. Cost Analysis Sensitivity Analysis 2

Sensitivity Analysis 2: Intervention effectiveness at lower bound of meta-analysis result = 18%

| Baseline Estimation | Age 65-74 | Age 75 and older |
|-------------------------------------|------------------|-------------------------|
| Number of reduced falls with injury | 93,941 | 149,977 |
| Reduced Medicare cost | (\$517,560,242) | (\$826,289,357) |
| Cost (savings) to Medicare | \$1,009,022,670 | \$905,795,102 |

Table 16. Cost Analysis Sensitivity Analysis 3

Sensitivity Analysis 3: Intervention penetration rate = 80%

| Baseline Estimation | Age 65-74 | Age 75 and older |
|-------------------------------------|-------------------|-------------------|
| Number of reduced falls with injury | 185,562 | 296,251 |
| Reduced Medicare cost | (\$1,022,341,219) | (\$1,632,176,508) |
| Intervention cost | \$ 1,356,962,589 | \$ 1,539,630,630 |
| Cost (savings) to Medicare | \$334,621,370 | (\$92,545,878) |

Table 17. Cost Analysis Sensitivity Analysis 4

Sensitivity Analysis 4: Fall rehabilitation rate = 70%

| Baseline Estimation | Age 65-74 | Age 75 and older |
|----------------------------|------------------|------------------|
| Intervention cost | \$ 1,667,653,281 | \$ 1,892,145,069 |
| Cost (savings) to Medicare | \$517,519,409 | \$55,946,498 |

Table 18. Cost Analysis Sensitivity Analysis 5

Sensitivity Analysis 5: Cost of fall rehabilitation = \$350

| Baseline Estimation | Age 65-74 | Age 75 and older |
|----------------------------|------------------|------------------|
| Intervention cost | \$ 1,738,188,465 | \$ 1,972,175,374 |
| Cost (savings) to Medicare | \$588,054,593 | \$135,976,803 |

These are admittedly crude estimates. They do not take into account any costs Medicare might have to pay as a result of implementing the plan developed from the falls prevention rehabilitation benefit (although such costs - for a change in medications, or new eyeglasses, or home environmental modifications, etc. - are not usually paid for by Medicare). Neither do these estimates account for any additional benefits beyond falls reduction that may accrue from the intervention. Exercise, for example, has also been associated with other health benefits. Still, these simple estimates support the hypothesis that falls prevention programs may be very cost-effective from Medicare's perspective, or even cost-saving from a total direct medical cost perspective.

QUESTION 6. SHOULD FALLS PREVENTION PROGRAMS BE TARGETED TOWARD HIGH-RISK INDIVIDUALS? ARE THERE A FEW BASIC QUESTIONS TO IDENTIFY THESE INDIVIDUALS? CAN THIS BE DONE THROUGH SELF-IDENTIFICATION?

We did not find evidence supporting the hypothesis that falls prevention programs are most effective in high risk populations, although in theory this should be true, and for other kinds of healthcare interventions there is empirical evidence that it is true. We assessed the efficacy of the two most effective interventions, multifactorial falls risk assessment and management program and exercise, in studies that enrolled high risk or

non-high risk populations. No statistically significant differences in efficacy between groups was detected (Table 19).

Table 19. Intervention by Population Type

| Intervention | Population Type | Subject who Fell at Least Once | | Monthly rate of falling | |
|---|--------------------------|--------------------------------|-------------------------------|--------------------------|---|
| | | Number of studies (arms) | Adjusted Risk Ratio (95 % CI) | Number of studies (arms) | Adjusted Incidence Rate Ratio (95 % CI) |
| Multifactorial falls risk assessment and management program | High Risk Population | 8 (8) | 0.82 (0.69, 0.97) | 7 (7) | 0.60 (0.45, 0.81) |
| Multifactorial falls risk assessment and management program | Not High Risk Population | 2 (2) | 0.60 (0.41, 0.89) | 0 (0) | NR |
| Exercise | High Risk Population | 5 (5) | 0.81 (0.61, 1.08) | 10 (10) | 1.09 (0.84, 1.42) |
| Exercise | Not High Risk Population | 7 (8) | 0.82 (0.75, 1.12) | 9 (10) | 0.71 (0.58, 0.88) |

That being said, interventions targeted to high and low risk populations have been different in most studies. For example, post-fall assessments and low-intensity exercise programs have been mostly targeted to frail and high-risk populations, while high intensity exercise programs have been targeted to broader populations (often excluding high-risk participants because of poor endurance). Therefore, comparing trials that focused on either high or low risk populations is not possible without some confounding by intervention variation.

Though not proven, it makes clinical and scientific sense that comprehensive post-fall assessments and fall risk assessments should be targeted to persons at higher risk. Because of their increased fall risk, they have the most to gain and would tend to have the largest effect size. In terms of identifying individuals at high risk for falls, there are a number of instruments, of varying length and complexity, with greater and lesser degrees of sensitivity and overall accuracy. From a practical standpoint, a simple identifier or set of questions is better, as long as it is reasonably accurate. With this in mind, the American Geriatrics Society evidence-based clinical guideline for prevention of falls (co-chaired by Laurence Rubenstein with considerable input from the Healthy Aging Project) recommended the following persons to have a comprehensive fall evaluation (risk assessment): 1) older persons presenting for medical attention with one or more falls, 2) older persons who report recurrent falls (2 or more in a 6 month period), or 3) older persons with abnormalities of gait and/or balance.²¹

QUESTION 7. ARE THERE SPECIFIC FALLS PREVENTION EXERCISES RECOMMENDED FOR SENIORS?

Exercise is effective in falls prevention programs. A variety of reviews and meta-analyses describing effective exercise interventions for falls prevention for seniors are found in the current literature.^{15, 123-127} We found too few studies that directly compared different exercise programs to support a pooled analysis, therefore, our meta-analysis was indirect, in that we compared the efficacy of different types of exercise to usual care. We did not find conclusive evidence supporting a recommendation for specific fall prevention exercises.

Our results regarding exercise need to be interpreted in light of the results of the meta-analysis previously conducted of the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) trials. The meta-analysis of the FICSIT trials on the effect of exercise on falls in elderly patients showed that subjects in groups with exercise interventions had an estimated 10% lower risk of falling than control subjects (adjusted fall incidence ratio was 0.90, 95% CI [0.81, 0.99] $p=0.04$). Exercise interventions included training in one or more of the following: endurance, flexibility, balance platform, Tai Chi, and resistance.¹⁵

Our meta-analysis also showed that exercise interventions reduced the risk of falls, in this case by 12% (pooled risk ratio: 0.88, 95% CI [0.78, 1.00]) and the rate of falls by 19% (pooled risk ratio: 0.81, 95% CI [0.72, 0.92]). While both the FICSIT meta-analysis and our meta-analysis (Table 9) suggested some trends in differing effectiveness among exercises, these results were not consistent. The FICSIT meta-analysis concluded that balance exercises had the strongest effect, while our own meta-analysis showed that endurance exercise was the only exercise type to have statistical significance in reducing subjects who fell at least once, while balance exercises were most effective in reducing monthly rate of falling. As in the FICSIT meta-analysis, our 95% confidence intervals for the estimates of efficacy overlap, indicating that there are no statistically significant differences between groups.

QUESTION 8. ARE FALLS PREVENTION PROGRAMS ACCEPTABLE TO SENIORS?

We did not find any direct evidence to answer this question, in the form of surveys, focus groups, or other methods that directly assess the general acceptability of falls prevention interventions among seniors. Some indirect evidence can be obtained from the clinical trials of falls prevention interventions. About half of the studies reported the "refusal rate" of those contacted and eligible for the intervention. These data are presented in Table 20 and represent a mix of studies that attempted to enroll subjects from large populations or small specialty clinics. Thus the variation in the "refusal rates" may represent populations in different stages of "readiness to change." Furthermore, these refusal rates include people who refused for reasons other than the acceptability of the intervention. For example, people may refuse to participate in any clinical trial because they equate this with "experimentation." As a result of factors like these, the average "refusal rate" is 30.5%. Furthermore, among the studies that reported both the number of persons beginning the study and those completing the study, the average "dropout" rate

was 16%. Taken together, these data suggest that the proportion of seniors for whom falls prevention programs are acceptable, while not precisely known, is likely substantial.

Table 20. Refusal Rate of Persons Eligible to Participate in Randomized Clinical Trials of Falls Prevention Interventions

| Author, Year | Text Description | Statistic Provided | Refusal Rate (percent) |
|---|--|---------------------------|-------------------------------|
| Carpenter GI, 1990 ID#443 | Refused | 59/602 | 9.8 % |
| Fabacher D, 1994 ID#444 | declined to participate | 94/348 | 27 % |
| Hornbrook MC, 1994 ID#445 | declined to participate | 5341/8680 | 61.5 % |
| Lord SR, 1995 ID#446 | declined (in exercise group) | 41/100 | 41 % |
| Mayo NE, 1994 ID#448 | refused consent | 71/431 | 16 % |
| Means KM, 1996 ID#450 | ineligible, unwilling, or unable | 55/154 | 35.7 % |
| Mulrow CD, 1994 ID#451 | Refused | 58/252 | 23 % |
| Sherrington C, 1997 ID#457 | Declined | 13/85 | 15 % |
| Wolfson L, 1996 ID#477 Judge JO, 1994 ID#478 | dropped out before randomization/ decided not to participate or did not complete baseline test | 164/274 | 59.8 % |
| Campbell AJ, 1997 ID#483 Campbell AJ 1999a ID#1504 | chose not to participate | 359/592 | 60.0 % |
| Rubenstein LZ, 1990 ID#492 | Refused | 45/205 | 22 % |
| Tinetti ME, 1994 ID#494 Tinetti ME, 1996 ID#497 | Refused | 54/355 | 15.2 % |
| Vetter NJ, 1992 ID#501 | Refused | 14/664 | 2.1 % |
| Wagner EH, 1994 ID#502 | Refused | 701/2260 | 31 % |
| Crilly RG, 1989 ID#522 | Refused | 10/60 | 16.7 % |
| Judge JO, 1993 ID#543 | did not wish to participate or did not complete the screening process | 30/114 | 26.3 % |
| Lord SR, 1996a ID#555 | participation rate of eligible subjects in the intervention group | 70.9% | 29.1 % |

Table 20. Refusal Rate of Persons Eligible to Participate in Randomized Clinical Trials of Falls Prevention Interventions

| Author, Year | Text Description | Statistic Provided | Refusal Rate (percent) |
|--------------------------------|---|---------------------------|-------------------------------|
| Armstrong AL, 1996a ID#576 | Declined | 114/230 | 49.5 % |
| Buchner DM, 1997 ID#616 | Refused | 2445/13866 | 17.6 % |
| Ebrahim S, 1997 ID#1204 | Refused | 8/165 | 4.8 % |
| Coleman EA, 1999 ID#1510 | Refused | 84/253 | 33 % |
| Close J, 1999 ID#1524 | Refused | 124/521 | 23.8 % |
| Campbell AJ, 1999b ID#1593 | chose not to participate | 400/493 | 81.1 % |
| Pomeroy VM, 1999 ID#1595 | informed consent could not be obtained | 10/91 | 10.9 % |
| Chandler JM, 1998 ID#1622 | not interested | 202/302 | 66.8 % |
| Cumming RG, 1999 ID#1699 | refused the intervention | 70/264 | 26.5 % |
| Wallace JI, 1998 ID#1767 | Declined | 39/139 | 28 % |
| Rubenstein LZ, 2000 ID#1988 | Refused | 84/361 | 23.2 % |
| Kannus P, 2000 ID#3089 | refusal to continue in the intervention | 71/446 | 15.9 % |
| | | Mean of Means | 30.5 % |

LIMITATIONS

The primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. Heterogeneity is another major issue. Even more so than in reviews of single therapies (e.g., coronary revascularization for coronary artery disease, pharmaceutical therapy for rheumatoid arthritis), the studies presented here are heterogeneous in terms of the interventions tested and populations included. Furthermore, many of the study-level variables are highly idiosyncratic and inter-correlated (e.g., all studies of restraints take place in institutions). Many interventions have multiple components, making the assessment of the effect of the individual components challenging. Furthermore, the populations studied were heterogeneous in that some enrolled population-based samples of patients, while others enrolled attendees at a special clinic or even respondents to advertisements. Our assessment of the relative effectiveness of individual components was made using indirect methods, as we did not find any direct comparisons of individual components. Such indirect comparisons are not as powerful as direct comparisons. However, the convergent results of our two meta-analyses lend validity to our conclusions.

We gave equal importance to all studies that met our minimum criteria (RCTs that measured the percent of a group with at least one fall or the number of falls per person). We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in falls prevention trials (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

Our results regarding exercise need to be interpreted in light of the results of the pre-planned meta-analysis of the FICSIT trials. FICSIT included seven RCTs that assessed a variety of exercise interventions, including endurance, flexibility, platform balance, Tai Chi, and resistance. The meta-analysis used individual patient-level data. We could include only two of the individual FICSIT trials in one of our meta-analyses (subjects who fell at least once)^{16,17} because we did not have access to the individual patient-level data. However, all but one FICSIT study contributed data to our second meta-analysis. Our results of exercise studies are in general agreement with the central FICSIT meta-analysis result: exercise programs help prevent falls (FICSIT pooled effect: 0.9, 95% CI [0.81, 0.99]; our pooled effect for percent with at least one fall 0.89, 95% CI [0.81, 0.98] and for monthly rate of falling 0.77, 95% CI [0.68, 0.87]). FICSIT also reported pooled effects for balance that were greater than (but not statistically different from) the overall effect. Our analysis assessing monthly rate of falling also found this result, however our analysis assessing number of subjects who fell at least once did not.

Regarding study populations, few studies of falls prevention stratified results by gender or ethnicity. Most studies either did not report the ethnic composition of the sample or used predominantly Caucasian samples. Thus, without further evidence, it should not be assumed such interventions will be similarly effective among all ethnic groups.

CONCLUSIONS

1. Falls prevention programs as a group have been shown to reduce the risk of experiencing a fall by 11% and monthly rate of falling by 23%.
2. Because few studies of single falls prevention interventions exist, statistical models were used to examine the independent effects of the four interventions with sufficient evidence to synthesize – multifactorial falls risk assessment and management; exercise; environmental modification; and education. Evidence supports a multifactorial falls risk assessment and management program as the most effective intervention. Exercise is the next most effective independent intervention. Thus, the evidence suggests that to be successful, falls prevention interventions should either use a multifactorial falls risk assessment and management program or exercise. However, the best approach to preventing falls is likely to use both a multifactorial falls risk assessment and management program along with exercise.
3. Falls risk assessments must be coupled with individually-tailored follow-up interventions to be effective.
4. Risk factor identification, which is one component of a multifactorial falls risk assessment and management program, may be self administered or administered by a professional. Both population-based public health approaches and medical model approaches are effective.
5. Our meta-analyses showed that exercise interventions reduce the risk of falls by 12% and the number of falls by 19%. While numerous exercise programs have been recommended to help prevent falls, there are insufficient data to identify the most effective exercises.
6. Successful falls prevention interventions have been delivered by a variety of providers, including exercise instructors, nurses, physical therapists, social workers, and teams of multiple providers. There is currently insufficient evidence to conclude that one provider type is preferable over another.
7. While not conclusive, the evidence suggests that falls prevention programs provided to seniors have the potential to be highly cost-effective compared with current practice. We estimate that a falls prevention rehabilitation program as a new Medicare benefit would be highly cost effective (even cost-saving in persons older than age 75) by preventing Medicare costs from injuries due to falls.
8. In the absence of new resources, it seems unlikely that much progress will be made in getting seniors to receive the benefits of falls prevention activities.

RECOMMENDATIONS

1. There is strong evidence that falls prevention programs are effective at preventing falls, and therefore ways are needed to better integrate these programs into the current care received by seniors.
2. There is strong evidence to support adding a falls prevention rehabilitation program as a new Medicare benefit. Such a program would be eligible to beneficiaries who have fallen, and would encompass a multifactorial risk assessment with a supervised exercise program.